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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,298	04/17/2007	Jaime Gosalvez Berenguer	U 016409-0	4147
140	7590	04/15/2010	EXAMINER	
LADAS & PARRY LLP 26 WEST 61ST STREET NEW YORK, NY 10023			CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	
			NOTIFICATION DATE	DELIVERY MODE
			04/15/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,298	<b>Applicant(s)</b> GOSALVEZ BERENGUER ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18 and 20-35 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 20-30 and 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2006 and 29 March 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2010 has been considered.

***Status of the Application***

2. The action is in response to the RCE filed on March 29, 2010. Currently claims 18-30 and 33-35 are under examination. New claims 35 is added. The dependent claims 33-34, previously withdrawn are considered for examination since they are dependent on rejected claims. Claim 31-32 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in view of the amendment.

3. The following informalities are noted:

(i) claim 35 do not end with a period or full stop.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-30, 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fernandez et al.( J. Andrology, Vol. 24, No. 1, pp. 59-66, 2003) in view of Bezanehtak et al. (J. Exp. Zool., Vol. 284, pp. 789-797, 1999).

Fernandez et al. teach a method of claims 18, to evaluate the integrity of chromatin DNA or DNA of sperm cells of an animal (human) comprising

(a) treating a sample containing the sperm, with a DNA denaturing solution (page 60, col. 2, line 1-6);

(b) a single step treatment of the sample in solution obtained in step a) with a lysis solution to extract nuclear proteins of the sperm cells (see page 60, col. 2, line 6-20),

(c ) evaluating the integrity of the chromatin/DNA of the sperm cells based on measurement of halo of the size of the sperm cells see page 60, col. 2, line 15-20, paragraph under fluorescence microscopy and digital image analysis sub-heading).

With regard to claims 22-23, Fernandez et al. teach that the lysis solution comprises sodium chloride between 1M to 3M, DTT between 0.001 to 2M and Tris between 0.001 to 2M (see page 60, col. 2, line 6-9).

With regard to claim 24-26, Fernandez et al. teach that the denaturing solution contains hydrochloric acid (see page 60, col. 2, line 1-6).

With regard to claim 27, Fernandez et al. teach that after the step a) and b) (see page 60, col. 2, line 15-20).

With regard to claim 28, Fernandez et al. teach that the stain is made with Wright type solution (Diff-quick solution) (see page 60, col. 2, line 15-20, paragraph under fluorescence microscopy and digital image analysis sub-heading, page 61, col. 1, paragraph 1).

With regard to claim 29-30, 34, Fernandez et al. teach that the sample containing the sperm is included in a medium similar to a suspension and said medium includes agarose microgel (see page 60, col. 1, paragraph under SCD test sub-heading).

With regard to claim 35, Fernandez et al. teach that the integrity of chromatin or DNA of sperm cells is evaluated through direct visual analysis by microscopy or applying digitalized images analysis software (see page 60, paragraph under fluorescence microscopy and digital image analysis sub-heading). However, Fernandez et al. did not teach lysis solution lacking a protein denaturing detergent.

Bezanehtak et al. teach the effect of non-ionic detergent, Triton-X on sperm demembranating and DNA condensation (see page 789, abstract, page 790, col. 1, paragraph 1). It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of evaluating the integrity of chromatin or DNA of sperm as taught by Fernandez et al. with the use of non-ionic detergent as by Bezanehtak et al. for the purpose of developing a sensitive method. The ordinary artisan would have motivated to combine the references because the ordinary artisan would have a reasonable expectation of

success that the combination would result in a sensitive, and efficient condensation of chromatin of sperm detection of polymorphism because Bezanehtak et al. explicitly taught that use of non-ionic detergent such as triton X would permeabilise sperm membrane and allows monitoring of condensed sperm chromatin under microscopy without damaging the axoneme (see page 789, abstract, page 793, col. 2, paragraph under discussion sub-heading) and such modification of the method would be obvious over the cited prior art. Further, As noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim (concentrations of the reagents) are disclosed in the prior art Fernandez et al. and Bezanehtak et al.), it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of hybridization conditions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637